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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,249	03/30/1998	HARUKI OKAMURA	OKAMURA=2B	6601
1444 7590 03/29/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER JIANG, DONG	
			ART UNIT 1646	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/29/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/050,249

Applicant(s)

OKAMURA ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 93,95 and 98-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 93,95 and 98-120 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED OFFICE ACTION**

The request filed on 22 February 2007 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/050,249 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 22 February 2007 is acknowledged and entered. Following the amendment, claims 93, 118 and 120 are amended.

Currently, claims 93, 95 and 98-120 are pending and under consideration.

It is noted that the status identifier ("Currently amended") for claim 119 is incorrect, and the correct status identifier should be "Previously presented" since the claim is not amended.

#### **Withdrawal of Objections and Rejections:**

The scope of enablement rejection, and lack of written description rejection of claim 118 under 35 U.S.C. 112, first paragraph, are withdrawn in view of applicant's amendment.

#### **Formal Matters:**

##### **Specification**

The specification is objected to for the following informalities, appropriate correction is required for each item:

On page 10, it is recited "and isolate the whole DNAs from the resultant suspension. Treat the DNAs with oligo-dT cellulose or oligo-dT latex to obtain poly(A)+RNA, and fractionate it using a sucrose density gradient buffer to isolate mRNA (lines 9-13 of the 2<sup>nd</sup> paragraph). It seems that whole RNA (not DNA) should be isolated.

#### **Rejections under 35 U.S.C. 112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 93, 95 and 98-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "*mainly* " in claim 93 is a relative term which renders the claim indefinite. The term " *mainly*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what is "mainly shows", i.e., does it means only one band, or it may contain other "minor" bands, and if so, how many are still within the meaning of "mainly shows a single protein band"? Claim 118 is similarly indefinite.

The remaining claims are included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

**Rejections Over Prior Art:**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 93, 95 and 98-120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (*Infect. Immun.* 61: 64-70, 1993), for the reasons set forth in the previous Office Actions.

Applicants argument filed on 22 February 2007 has been fully considered, but is not deemed persuasive for reasons below.

At page 9 of the response, applicants present the same summary Table as they did in the previous response filed on 5/8/06, with a correction of a typographical error. The Table has been fully considered, but is not persuasive for reasons of record.

At pages 9-10 of the response, the applicant argue that claims 93 and 118 have been amended to define IGIF/IL-18 as “mainly showing a single protein band ... in a SDS-PAGE free of reducing agent ...”, and that by contrast, Okamura reports that a protein having a MW of  $19,000 \pm 5,000$  that is derived from Nakamura’s factor does not show the activity in the absence of a reducing agent (page 3969, left column, lines 12-17), and thus, applicants believe that IGIF/IL-18 in the present claims is distinguished from that of Nakamura. This argument is not persuasive for the reasons of record (see previous Office Actions mailed on 10/21/02, 5/20/03 and 2/11/04, for example). Whatever applicants *believe* is less relevant because the matter of *fact* is that, as addressed in the previous Office Actions, Okamura demonstrated that the molecular mass of 75 kDa IGIF was reduced to 19 kDa on 0.1% SDS-PAGE in the presence of DTT, and the N-terminal amino acid *sequence is the same* as that of IGIF from the liver, and Okamura clearly stated that “thus IGIF in the serum sample was proved to be the same IGIF as that found in the liver exact” (the abstract, and page 3969, the second paragraph of the left column).

At pages 10-11 of the response, the applicant argue, citing “The Cytokine Handbook”, that the molecular species of 19 kDa derived from Nakamura’s factor may be different from the IGIF/IL-18 in the present claims, and may not be effective in obtaining a monoclonal antibody recognizing IGIF/IL-18. This argument is not persuasive for the reasons above. Applicants further argue, at page 11 of the response, that both Nakamura and Okamura do not disclose that they actually obtained monoclonal antibodies recognizing IGIF even though they indicate that necessity of such, which suggests that the present invention would not have been obvious over Nakamura to one of ordinary skill in the art. This argument is not persuasive because, as the

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suggestion/motivation is clear, the only remaining issue is making/obtaining the antibodies. Given the fact that the state of the prior art in the technology of making monoclonal antibody was very high at the time the present invention was filed, the person of ordinary skill in the art reasonably would have expected success in obtaining the monoclonal antibodies as that claimed.

At pages 11-12 of the response, the applicant argue that Nakamura discloses that the cells producing the factor have not been identified, that accordingly, the present claims would not have been obvious over Nakamura to one of ordinary skill in the art. This argument is not persuasive because it is less important whether the cells producing the factor have been identified as Nakamura has already obtained the factor, which could be used as the antigen source for the purpose of generating antibody.

At page 12 of the response, the applicant argue that claim 120 defines the antibody by using, as an antigen, IGIF/IL-18 extracted from the liver of a mouse previously challenged with *Corynebacterium parvum*, and that Nakamura's factor was obtained from mouse serum, and not the liver of mouse. This argument is not persuasive for the reasons above as Okamura demonstrated that IGIF in the serum sample was proved to be the same IGIF as that found in the liver exact, and therefore, the source of isolation of IGIF is irrelevant with respect to the use of IGIF for the purpose of generating antibodies.

**Conclusion:**

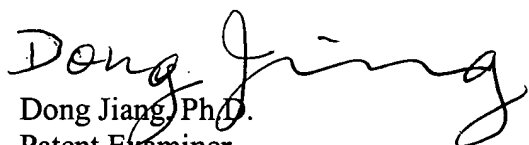
No claim is allowable.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in cursive script that reads "Dong Jiang".

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
3/18/07